Attorney Docket No.: 10121-01301 (99-0090)

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)
Trabada et al.	)
Serial No.: 10/753,848	) Group Art Unit: 3731
Filed: January 8, 2004	) Examiner: Amy T. Lang
For: ENDOLUMINAL ACCESS DEVICE AND RELATED METHODS OF USE	) ) )
Confirmation No.: 6030	)

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#### APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In response to the Notice of Non-Compliant Appeal filed June 27, 2011, Appellant presents this Response to Non-Compliant Appeal Brief in the above-captioned application.

The Examiner has noted that Section 3 of the Appeal Brief filed on June 14, 2011 incorrectly listed claims 12 and 13 as being the subject of this appeal and as also being previously canceled. As noted in the Claims Appendix, these claims have not been canceled and are, in fact, a subject of this appeal. The typographical error has been corrected in the amended Section 3 presented below.

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

#### 1. Real Party in Interest

This application is assigned to Boston Scientific Scimed, Inc., the real party in interest.

#### 2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected, or have a bearing on the instant appeal.

#### 3. Status of the Claims

Claims 1 - 8, 10 - 13, 22, 24 and 25 have been rejected in the final office action and are the subject of this appeal. Claims 9, 14 - 21 and 23 have been previously canceled.

#### 4. <u>Status of Amendments</u>

All Amendments submitted by the Appellants have been entered.

#### 5. Summary of Claimed Subject Matter

The following summary refers to the specification and identifies certain claim limitations with the reference characters of one or more drawings. The association in this summary of a claim limitation with a particular reference character, figure, or passage from the specification is only exemplary and is not intended to limit the scope of the claims.

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

The present invention, as exemplified in claim 1, is directed to an endoluminal access system for accessing a body lumen, comprising a guide track which, when in an operative position, extends through a body lumen to a desired location therewithin. *Specification*, pp. 1 - 2, ¶ [0004]; pp. 4 - 6, ¶¶ [0011] - [0016]; *see* Figs. 1 - 6C. The endoluminal access system further includes a modular device selectively coupleable to the guide track, wherein the modular device including a drive mechanism for engaging the guide track to move the modular device along the guide track within the body lumen. *Id.*, at pp. 1 - 2, ¶ [0004]; pp. 4 - 9, ¶¶ [0011] - [0019]; *see* Figs. 2 - 4 and 5C - 8B. The endoluminal access system further includes an anchoring module selectively coupleable to the guide track for anchoring the guide track at the desired location, the anchoring module including an anchoring module drive mechanism for engaging the guide track to move the anchoring module along the guide track to the desired location, wherein the anchoring module drive mechanism is located inside the anchoring module. *Id.* at p. 6, ¶ [0015]; pp. 9 - 10, ¶¶ [0019] - [0020]; pp. 13 - 15, ¶¶ [0031] - [0033]; *see* Figs. 7A and 8A.

The present invention, as exemplified in claim 6, is directed to an endoluminal access system for accessing a body lumen, comprising a guide track which, when in an operative position, extends through a body lumen to a desired location therewithin. *Id.*, at pp. 1 - 2, ¶ [0004]; pp. 4 - 6, ¶¶ [0011] - [0016]; *see* Figs. 1 - 6C. The endoluminal access system further comprising a modular device selectively coupleable to the guide track, the modular device including a drive mechanism for engaging the guide track to move the modular device along the guide track within the body lumen, wherein the drive mechanism includes a threaded member for

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

engaging a contact surface of the guide track and rotating about the guide track, and wherein the threaded member includes a threaded hole. *Id.*, at pp. 7 - 9, ¶¶ [0017] - [0019]; *see* Figs. 4 - 5D.

The present invention, as exemplified in claim 22, is directed to a method of resecting tissue from a site within a body. Id., at p. 2, ¶ [0005]. The method of resecting tissue comprising the steps of inserting a guide track to a desired location within the body lumen, selectively coupling an anchoring module to the guide track, actuating a motor of the anchoring module in order to advance the anchoring module along the guide track to a desired location within the bodily lumen, anchoring the guide track at the desired location within the body lumen via the anchoring module, coupling a modular device to a proximal end of the guide track, actuating a motor mounted within the modular device to drive the modular device distally along the guide track to the site, drawing tissue at the site into the modular device, coupling together a portion of tissue adjacent to the site, resecting the tissue from the site, and actuating the motor to drive the modular device proximally to withdraw the modular device from the body lumen. Id., at pp. 13 - 15, ¶ [0031] - [0033].

### 6. Ground of Rejection to be Reviewed on Appeal

I. Whether claims 1 - 5, 7, and 10 - 13 are unpatentable under 35 U.S.C. § 103(a) as obvious over E.P. Patent No. EP 0976417 A1 to Richter (hereinafter "Richter") in view of U.S. Patent No. 5,167,239 to Cohen et al. (hereinafter "Cohen") and U.S. Patent No. 7,169,160 to Middleman et al. (hereinafter "Middleman").

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

II. Whether claim 8 is unpatentable under 35 U.S.C. § 103(a) as obvious over Richter in view Cohen and Middleman and further in view of U.S. Patent No. 7,229,401 to Kindlein (hereinafter "Kindlein") or U.S. Patent No. 6,971,990 to Ziegler et al. (hereinafter "Ziegler").

- III. Whether claim 6 is unpatentable under 35 U.S.C. § 103(a) as obvious over Richter in view Kindlein or Ziegler.
- IV. Whether claims 22, 24 and 25 are unpatentable under 35 U.S.C. § 103(a) as obvious over Richter in view of U.S. Patent Appln Pub. No. 2002/0065523 to McAllister et al. (hereinafter "McAllister") in further view of Cohen and Middleman.

#### 7. Argument

I. The Rejection of Claims 1 - 5, 7, and 10 - 13 Under 35 U.S.C. § 103(a) as Obvious Over Richter in View of Cohen and Middleman Should be Reversed

#### A. The Examiner's Rejection

In the Final Office Action, claims 1-5, 7, and 10-13 were rejected under 35 U.S.C. § 103(a) as unpatentable over Richter in view of Cohen and Middleman. 10/15/2010 Final Office Action, p 2, ¶ 3.

B. The References do not Disclose an Anchoring
Module Selectively Coupleable to the Guide Track
Including an Anchoring Module Drive Mechanism
to Move the Anchoring Module Along the Guide
Track as Recited in Claim 1

Claim 1 recites an endoluminal access system for accessing a body lumen, comprising, "a guide track which, when in an operative position, extends through a body lumen to a desired

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

location therewithin; a modular device selectively coupleable to the guide track, the modular device including a drive mechanism for engaging the guide track to move the modular device along the guide track within the body lumen; and an anchoring module selectively coupleable to the guide track for anchoring the guide track at the desired location, the anchoring module including an anchoring module drive mechanism for engaging the guide track to move the anchoring module along the guide track to the desired location, wherein the anchoring module drive mechanism is located inside the anchoring module." (Emphasis added).

Appellants contend that none of Richter, Middleman and Cohen, taken either alone or in any combination, teaches or suggests an anchoring module coupleable to a guide track including an anchoring module drive mechanism to move the anchoring module along the guide track, as recited in claim 1. Richter relates to an apparatus for pulling and positioning an object, such as a stent, to a target area of a lumen. *Richter*, Abstract. Specifically, the Richter apparatus includes a motor that crawls along a guide wire to change its position relative to the guide wire. *Id.*, at pp. 3 - 4, ¶ [0017]. The Examiner has acknowledged that Richter neither teaches nor suggests any anchoring or securing component for securing the guide wire to a location. *10/15/2010 Final Office Action*, p. 3, ll. 4 - 5. In order to overcome the deficiencies of Richter, the Examiner relies on the Middleman and Cohen references. However, it is respectfully submitted that these references teach away from the Richter reference and, in fact, are not capable of the modifications proposed by the Examiner.

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

Cohen is directed to a balloon 14 mounted over a guidewire body 12. *Cohen*, col. 5, ll. 13 - 26; Figs. 1, 3. It is important to note that the balloon 14 of Cohen is mounted at a predetermined position on the guidewire body 12 and is not movable relative thereto. Specifically, as regards the construction and mounting of the balloon 14, the Cohen reference states:

At the location where the balloon is to be mounted, a portion of the outer wire coil 24 equal in length to the length of the balloon 14 to be mounted, is eliminated or absent so as to expose the underlying outer surface 34 of the inner tube 22 [of the guidewire 12]. One end of the elastic tube used to form the balloon 14 is initially disposed about the proximal most region of the exposed portion of the inner tube 22 and is <u>firmly affixed</u> thereto by wrapping or tying a thread or suture material 36a therearound. The latex tube is then folded over itself, in a distal direction as shown, and the opposite end of the balloon 14 is attached to the distal-most portion of the exposed portion of the inner tube 22 by wrapping or tying of thread or suture material 36b therearound.

*Id.*, col. 11, ll. 46 - 54; see Fig. 3. (Emphasis added).

That is, the Cohen balloon 14 is constructed as an immovable component mounted to the guidewire 12 at a specific location. In the Advisory Action, the Examiner stated "it seems as though the balloon inflation lumen would move with the balloon anchoring device so that a drive mechanism within the device would not be detrimental." *Advisory Action*, p. 2, ll. 7 - 8. However, in contrast to the Examiner's opinion, the Cohen reference clearly states that the balloon is firmly affixed to the inner tube 22 of the guidewire body 12. Therefore, it would not be possible to modify the teachings of the Cohen reference as presumed by the Examiner.

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

Specifically, it is evident that Cohen cannot be combined with any reference in order to include an "anchoring module drive mechanism... to move the anchoring module along the guide track," as recited in claim 1. Thus, it is therefore respectfully submitted that the modification proposed by the Examiner is not allowable for at least this reason.

Middleman is directed to an anchoring apparatus 10 comprising a first tubular element 36 housed within a second tubular element 20 so that distal movement of the first element 36 relative to the second tubular element 20 exposes anchoring members 56, 60 provided on a distal end of the first tubular element 36. Middleman, col. 5, Il. 26-50; Figs. 1, 3, 4, 6-11. The anchoring members 56, 60 extend through openings 86 of the outer lumen 22 to engage the inner wall 14 of a passageway 12, thereby anchoring the apparatus 10. It is respectfully submitted that the tubular element 20 and anchoring members 56, 60 of Middleman are neither equivalent nor analogous to the guidewire 12 of the Cohen reference and inflatable balloon 14 of the Richter reference in any manner warranting the combination proposed by the Examiner. Specifically, the anchoring members 56, 60 are positioned within a tubular element 20 and are slidable therewithin. It is unclear how the anchoring member 56, 60 would be adapted to either of the devices of Richter and Cohen, both of which require elements disposed over respective guidewires. In the Advisory Action, the Examiner argues that the Middleman reference was used to show "that it is well known in the art for anchoring means to move along a guide track." Advisory Action, p. 2, ll. 4 - 5. However, as explicitly recited in claim 1, the anchoring module of the claimed system is "selectively coupleable to the guide track." This is not the case in the

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

Middleman reference, and furthermore, this is not possible with the teachings of Middleman, even if the outer lumen 22 is presumed to be a "guiding track" as suggested by the Examiner. In contrast to claim 1, Middleman requires that the anchoring members 56, 60 and its second tubular element 20 are detached from the "guiding" outer lumen 22. Specifically, it is this detachment that allows for the anchoring members 56, 60 and its tubular element 20 to slidably move with respect to the outer lumen 22. Therefore, it would not be possible to modify the teachings of the Middleman reference as presumed by the Examiner. It is therefore evident that Middleman does not teach or suggest "an anchoring module selectively coupleable to the guide track," as recited in claim 1. It is therefore respectfully submitted that the modification proposed by the Examiner is not supported by the disclosures relied upon for at least this reason.

Furthermore, as noted in the 01/13/2011 Response from Appellants, the Examiner has improperly analogized both the guidewire body 12 of the Richter reference and the tubular element 18 of the Middleman reference to the "guide track" of claim 1 to overcome arguments previously presented by the Appellants. It is respectfully submitted that neither the guidewire body 12 nor the tubular element 18 is capable of meeting the limitations of "a guide track which...extends through a body lumen to a desired location therewithin" and "a modular device selectively coupled to the guide track, the modular device including a drive mechanism for engaging the guide track to move the modular device along the guide track" in combination with an "anchoring module including an anchoring module drive mechanism for engaging the guide track to move the anchoring module along the guide track to the desired location," as recited in

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

claim 1. In an earlier response, Appellants argued that Middleman also fails to teach a guidewire capable of meeting these limitations in claim 1. 08/13/2010 Response to Office Action. In response, the Examiner stated that he "relies on member 18 for the guide track while Applicant argues with reference to member 46 for the guide track." 10/15/2010 Final Office Action, p. 9. However, it is respectfully submitted that the cited embodiment of Middleman is actuatable only by movement of a first tubular portion relative to a second tubular portion and would find no utility if coupled to a guide track as recited in claim 1 or with a guidewire 12 as taught by Cohen.

It is evident that the anchoring members 56, 60 of Middleman are movable relative to the tubular element 20 only due to their positioning therewithin. The Examiner seeks to draw out this movable property of the anchoring members 56, 60 and to apply it to the balloon 14 which is positioned *over* the guide wire 12. 10/15/2010 Final Office Action, pp. 3-4, ll. 9-10. It is respectfully submitted that such a modification is improper when it is evident that the movable properties of the anchoring members 56, 60 are directly related to their positioning within the tubular element 18. That is, it is improper to apply only a functional limitation from the Middleman device without also applying the structural limitations which impart the recited function thereto. It is therefore respectfully submitted that neither Richter nor Cohen nor Middleman teach or suggest "an anchoring module selectively coupleable to the guide track for anchoring the guide track at the desired location, the anchoring module including an anchoring module drive mechanism for engaging the guide track to move the anchoring module along the

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

guide track to the desired location," as recited in claim 1 and that claim 1 is allowable for at least this reason.

Still further, it is respectfully submitted that neither Richter nor Cohen nor Middleman teach or suggest "wherein the anchoring module drive *mechanism is located inside the anchoring module*," as also recited in claim 1. In support of the rejection, the Examiner argues that the pushing mechanism of Middleman may be replaced with the motor drive mechanism of Richter to crawl along the guidewire. *10/15/2010 Final Office Action*, p. 3, ll. 15-21. Specifically, the Examiner concedes that only Richter teaches any drive mechanism at all and has argued a proposed modification wherein an additional drive mechanism is provided to drive the anchoring module. However, it is respectfully submitted that Richter only teaches a drive mechanism disposed over a guidewire 12 and thus provides no support for an "anchoring module drive mechanism [that] is located inside the anchoring module," as recited in claim 1. Since Cohen is silent with respect to a drive mechanism, it is evident that Cohen fails to cure this deficiency. Middleman teaches a pushing mechanism formed as a lumen 20 located proximally of the anchoring members 56, 60 and therefore also fails to cure this deficiency. It is respectfully submitted that claim 1 is therefore allowable for at least this additional reason.

It is therefore respectfully submitted that Richter, Cohen and Middleman, taken either alone or in any combination, fail to show or suggest "an anchoring module selectively *coupleable* to the guide track for anchoring the guide track at the desired location, the anchoring module including an anchoring module drive mechanism for engaging the guide track to move the

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

anchoring module along the guide track to the desired location, wherein the anchoring module drive mechanism is located inside the anchoring module," as recited in claim 1 and that the rejection of claim 1 should be reversed for at least this reason.

Because claims 2-5, 7, 10-12 and 13 depend from and therefore include all of the limitations of claim 1, it is respectfully submitted that the rejection of these claims should also be reversed.

II. The Rejection of Claim 8 Under 35 U.S.C. § 103(a) as Obvious Over Richter in View Cohen and Middleman and further in view of Kindlein or Ziegler Should be Reversed

#### A. The Examiner's Rejection

In the Final Office Action, claim 8 was rejected under 35 U.S.C. § 103(a) as unpatentable over Richter in view Cohen and Middleman and further in view of Kindlein or Middleman. *Id.*, at p 5, ¶ 4.

B. The References do not Cure the Deficiencies Presented Above in Reference to Claim 1

Claim 8 depends from and therefore includes all of the limitations of independent claim

1. As noted above, Richter, Cohen and Middleman, taken alone or in any combination, fail to
teach or suggest the limitations of claim 1. Ziegler fails to cure these deficiencies. It is therefore
respectfully submitted that claim 1 is allowable over Richter, Cohen, Middleman and Ziegler,

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

taken alone or in any combination. The rejection of claim 8 should be reversed as claim 8 is dependent on an allowable base claim.

III. The Rejection of Claim 6 Under 35 U.S.C. § 103(a) as Obvious Over Richter in View Kindlein or Ziegler Should be Reversed

#### A. The Examiner's Rejection

In the Final Office Action, claim 6 was rejected under 35 U.S.C. § 103(a) as unpatentable over Richter in view of Kindlein or Middleman. *Id.*, at p 6, ¶ 5.

B. The References do not Rotatable About a Guide Track Received Within the Guide Track Receiving Lumen to Move the Modular Device therealong as Recited in Claim 6.

Claim 6 recites a modular device for tissue resection, comprising "a housing including a guide track receiving lumen extending therethrough" and "a motor mounted within the housing, the motor being selectively engageable with and *rotatable about a guide track received within* the guide track receiving lumen to move the modular device therealong" in combination with "a tissue receiving chamber formed within the housing" and "a grabbing mechanism drawing a selected portion of tissue into the tissue receiving chamber" along with "a resection mechanism resecting the selected portion of tissue." (Emphasis added).

The Examiner acknowledged that Richter does not disclose a drive mechanism as a threaded member that rotationally engages about the guide track. *Id.* The Examiner cited either Kindlein or Ziegler to cure this deficiency. It is respectfully submitted, however, that both

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

Kindlein and Ziegler disclose a motor that includes gears that turn relative to a length of a longitudinal element received through a lumen thereof. Neither Kindlein nor Ziegler show or suggest a motor *rotatable about* a guide track to move the device longitudinally therealong.

Specifically, Kindlein discloses a needle insertion device including a wheel that turns relative to a longitudinal axis of the device to move the needle along a longitudinal axis thereof and insert the needle into a target area. It is respectfully submitted that the motor of the needle insertion device does not *rotate about* the needle to move the needle insertion device longitudinally therealong. The needle insertion device 14 of Kindlein has a motor 31 including four drive wheels 33a - 33d. *Kindlein*, col. 8, ll. 45 - 50. Two of the wheels 33a, 33b are mounted on a plate 30 while the other two wheels 33c, 33d are drive press wheels mounted on a movable plate 34 such that a needle 10 passes between the first set of wheels 33a, 33b and the second set of wheels 33c, 33d. *Id.* at col. 8, ll. 46 - 54; *see* Figs. 6A - 6B. The movable plate 34 is movable between a first configuration which moves the drive-press wheels 33c, 33d into contact with a needle 10, as shown in Fig. 6A, and a second configuration which moves the drive-press wheels 33c, 33d away from the needle 10 to release the needle 10, as shown in Fig. 6B. *Id.* at col. 8, ll. 52 - 56. As shown in Figs. 6A and 6B, the motor 31 rotates the wheel 33a only relative to a length of the needle 10 to move the needle 10 longitudinally relative thereto.

In the Advisory Action, however, the Examiner contended that the rotation of the wheel 33a relative to the length of the needle indicates that the wheel 33a is "rotatable about" the needle 10. *Advisory Action*, p. 2. Appellants respectfully disagree. This interpretation clearly

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

contradicts the plain meaning of the claim language. This meaning, as would clearly be understood by those of skill in the art, and as supported by the Specification, requires a motor that is "rotatable about a guide track" – i.e., a motor which rotates around the guide track. Specifically, the term "rotate" is defined as "to turn *about* an axis or center." *Websters' Third New International Dictionary*, Merriam-Webster, Inc., 1986 (emphasis added). For example, the Specification describes "[a] guide track, e.g., in the form of a catheter 220 may be slidably received in the *central lumen* of the armature sleeve 215b with the armature sleeve 215b rotating *thereabout* when the motor 215 is driven to move the FTRD modular device 210 along the catheter 220[.]" *Specification*, p. 10, ¶ [0022]; *see* Figs. 7A - 7C. Thus, it is respectfully submitted that the armature sleeve 215b of the motor 215 surrounds the catheter 220 and rotates around the catheter 220 – i.e., the catheter 220 defines the axis of rotation of the motor 215.

As clearly described and shown in Fig. 6 of Kindlein, a center about which the wheel 33a rotates is separated from the needle 10 and the needle 10 is radially outside the wheel 33a. Thus, it is respectfully submitted that the wheel 33a is not "rotatable about" the needle 10.

Similarly, Ziegler discloses a device comprising a toroid surface that rotates around itself to advance through a tubular structure. It is respectfully submitted that Ziegler does not show or suggest a motor *rotating about* a guide track to move the device therealong. Ziegler describes an apparatus 100 comprising a toroid 102 including a bladder 104 formed of a flexible material 106. *Ziegler*, col. 4, ll. 57 - 62. A frame 108 supports and interacts with the flexible material 106 and includes a support structure 128 and a housing structure 130, which is disposed in a central cavity

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

126 of the flexible material 106. *Id.* at col. 5, ll. 3 - 9. The frame 108 supports a pair of motive rollers 134, which contact the flexible material 106 such that rotation of the motive rollers 134 relative to a longitudinal axis of the apparatus 100 causes the flexible material 106 to move along a length of a tubular structure (e.g., endoscope) via contact between the flexible material 106 and the tubular structure. *Id.* at col. 5, ll. 14 - 20. As the axis about which the motive rollers 134 rotate does not coincide with a longitudinal axis of the central cavity 126, it is respectfully submitted that the motive rollers 134 do not *rotate about* the cavity 126.

Accordingly, it is respectfully submitted that Richter, Kindlein and Ziegler, taken either alone or in combination, do not show nor suggest, "the drive mechanism includes a threaded member for engaging a contact surface of the guide track and rotating about the guide track," as recited in claim 1. Thus, it is respectfully submitted that claim 1 is not rendered obvious by Richter in view of either Kindlein or Ziegler and that the final rejection of this claim should be reversed. Because claims 2 - 8 depend from and include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

- IV. The Rejection of Claims 22, 24 and 25 Under 35 U.S.C. § 103(a) as Obvious Over Richter in View of McAlister, Cohen and Middleman Should be Reversed
  - A. The Examiner's Rejection

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

In the Final Office Action, claims 22, 24 and 25 were rejected under 35 U.S.C. § 103(a) as unpatentable over Richter in view McAlister, Cohen and Middleman. 10/15/10 Final Office Action, p 7, ¶ 6.

B. The References do not Disclose Coupling an Anchoring Module to the Guide Track, Actuating a Motor to Advance the Anchoring Module Along the Guide Track to a location and Anchoring the Guide Track at the location as Recited in Claim 1

Claim 22 recites, *inter alia*, "...selectively coupling an anchoring module to the guide track; actuating a motor of the anchoring module in order to advance the anchoring module along the guide track to a desired location within the bodily lumen; anchoring the guide track at the desired location within the body lumen via the anchoring module..."

As noted above in response to the 35 U.S.C. § 103(a) rejection of claims 1 - 5, 7 and 10 - 13, Richter, Cohen and Middleman fail to teach or suggest the steps of "inserting a guide track to a desired location within the body lumen; selectively coupling an anchoring module to the guide track; actuating a motor of the anchoring module in order to advance the anchoring module along the guide track to a desired location within the bodily lumen [and] anchoring the guide track at the desired location within the body lumen via the anchoring module," as recited in claim 22.

McAlister fails to cure these deficiencies. It is therefore respectfully submitted that Richter, McAlister, Cohen and Middleman, taken alone or in any combination, fail to teach or suggest "inserting a guide track to a desired location within the body lumen; selectively coupling an anchoring module to the guide track; actuating a motor of the anchoring module in order to

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

advance the anchoring module along the guide track to a desired location within the bodily lumen [and] anchoring the guide track at the desired location within the body lumen via the anchoring module," as recited in claim 22 and that the rejection of claim 22 should be reversed. Because claims 24 and 25 depend from and therefore include all of the limitations of independent claim 22, it is respectfully submitted that the rejection of these claims should also be reversed.

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

## 8. <u>Conclusions</u>

For the reasons set forth above, Appellants respectfully requests that the Board reverse the final rejection of the claims by the Examiner and indicate that all pending claims are allowable.

Respectfully submitted,

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Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

#### **CLAIMS APPENDIX**

1. (Previously presented) An endoluminal access system for accessing a body lumen, comprising:

a guide track which, when in an operative position, extends through a body lumen to a desired location therewithin;

a modular device selectively coupleable to the guide track, the modular device including a drive mechanism for engaging the guide track to move the modular device along the guide track within the body lumen; and

an anchoring module selectively coupleable to the guide track for anchoring the guide track at the desired location, the anchoring module including an anchoring module drive mechanism for engaging the guide track to move the anchoring module along the guide track to the desired location, wherein the anchoring module drive mechanism is located inside the anchoring module.

- 2. (Original) The system of claim 1, wherein the guide track includes one of a catheter and a guide wire.
- 3. (Original) The system of claim 1, wherein the guide track includes a substantially helical contact surface formed on an outer surface thereof and wherein the drive mechanism engages the contact surface to move the modular device along the guide track.
- 4. (Original) The system of claim 1, wherein the drive mechanism includes a motor located within the modular device.

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

5. (Original) The system of claim 4, wherein the motor is an electric motor and wherein the drive mechanism includes a cable extending out of the modular device to an external power source.

6. (Previously presented) An endoluminal access system for accessing a body lumen, comprising:

a guide track which, when in an operative position, extends through a body lumen to a desired location therewithin; and

a modular device selectively coupleable to the guide track, the modular device including a drive mechanism for engaging the guide track to move the modular device along the guide track within the body lumen, wherein the drive mechanism includes a threaded member for engaging a contact surface of the guide track and rotating about the guide track, and wherein the threaded member includes a threaded hole.

- 7. (Original) The system of claim 1, wherein the modular device includes a guide track receiving lumen extending therethrough for receiving the guide track therein.
- 8. (Original) The system of claim 1, wherein the drive mechanism includes gears moveable between an engaging position for engaging the guide track to move the modular device therealong and a retracted position separated from the guide track.
  - 9. (Canceled)

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

10. (Previously presented) The system of claim 1, wherein the anchoring module includes a first extendible member moveable between a retracted position in which the anchoring module is free to move within the body lumen and an extended position in which the first extendible member contacts a wall of the body lumen to anchor the guide track in a desired position therewithin.

- 11. (Original) The system of claim 10, wherein the first extendible member includes a first balloon, the system further comprising a first inflation lumen extending between an inlet which remains outside the patient's body to an outlet coupled to the first balloon.
- 12. (Previously presented) The system of claim 10, further comprising a second extendible member coupled to the modular device, the second extendible member being moveable between a retracted position in which the modular device is free to move within the body lumen and an extended position in which the second extendible member contacts a wall of the body lumen to anchor the modular device at a desired position therewithin.
- 13. (Original) The system of claim 12, wherein the second extendible member includes a second balloon, the system further comprising a second inflation lumen extending between an inlet which remains outside the patient's body to an outlet coupled to the second balloon.
  - 14 21. (Cancelled).
- 22. (Previously presented) A method of resecting tissue from a site within a body comprising the steps of:

inserting a guide track to a desired location within the body lumen;

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

selectively coupling an anchoring module to the guide track;

actuating a motor of the anchoring module in order to advance the anchoring module along the guide track to a desired location within the bodily lumen;

anchoring the guide track at the desired location within the body lumen via the anchoring module;

coupling a modular device to a proximal end of the guide track;

actuating a motor mounted within the modular device to drive the modular device distally along the guide track to the site;

drawing tissue at the site into the modular device; coupling together a portion of tissue adjacent to the site;

resecting the tissue from the site; and

actuating the motor to drive the modular device proximally to withdraw the modular device from the body lumen.

23. (Canceled).

24. (Previously presented) The method of claim 22, wherein the step of anchoring the guide track further comprises the sub-step of:

Group Art Unit: 3731

Attorney Docket No.: 10121-01301 (99-0090)

extending an anchoring member of the anchoring module to anchor the anchoring module at the anchoring location thereby anchoring the guide track at the desired location.

25. (Original) The method of claim 22, further comprising the step of extending a positioning member from the modular device to maintain the modular device in a desired position within the body lumen.

Group Art Unit: 3731 Attorney Docket No.: 10121-01301 (99-0090)

# EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

Group Art Unit: 3731 Attorney Docket No.: 10121-01301 (99-0090)

# RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.